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Global perspective of the risks of falsified and counterfeit medicines: A critical review of the literature

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ABSTRACT

Background: The increasing prevalence of falsified and counterfeit medicines globally poses risks to international travellers. This narrative literature review examines the global challenge of falsified and counterfeit medicines, with a specific focus on risks for travellers. The aim is to provide a comprehensive understanding of this multidimensional issue, exploring potential solutions for effective intervention.

Methods: A comprehensive search of databases, including PubMed, MEDLINE, and Scopus, as well as relevant reports from international organisations, was undertaken. There was a focus on extracting information pertaining to the prevalence, types, and geographical patterns of falsified and counterfeit medicines encountered by international travellers. Synthesising this information helped to identify overarching trends and patterns. This narrative review utilised a thematic analysis approach to synthesise the findings.

Results: The findings revealed a diverse range of counterfeit drug categories, spanning from antibiotics to lifestyle medications, posing unique risks to travellers navigating the global pharmaceutical landscape. The review emphasises the geographical distribution of these drugs, with varying consequences for both high- and low-income nations. The inadequate formulations and inconsistent drug release arising from these practices pose severe threats to public health, especially for individuals travelling abroad. The review also highlights the significance of international collaboration in addressing this global challenge, as pharmaceutical supply chains seamlessly cross borders, necessitating a collaborative approach for effective regulation and enforcement.

Conclusions: This review underscores the need for targeted research, collaborative interventions, and technological innovations to address the complexities associated with falsified and counterfeit medicines, ensuring the safety and well-being of international travellers.

1. Introduction

Falsified and counterfeit medicines pose a significant public health risk, including in the context of international travel [1]. As the incidence of reported cases has risen globally, concerns over the proliferation of falsified and counterfeit medicines have intensified [2]. Substandard pharmaceutical products masquerade as genuine medications, potentially deceiving both healthcare professionals and consumers. The consequences of this phenomenon can be significant, ranging from treatment failures and exacerbation of illnesses to development of drug resistance and even loss of life [3]. With more travellers purchasing medications abroad, sometimes in countries where the export of certain drugs is not authorised or is prohibited, the risk of encountering falsified and counterfeit medications increases. This is further complicated by the ongoing challenges in maintaining and updating international databases that track the legality and safety of cross-border pharmaceutical sales [4]. As international travel becomes more accessible, these risks become more pronounced for tourists, expatriates, and healthcare providers alike.

These products are deliberately mislabelled with respect to their identity, source, or composition and range from substandard or adulterated drugs to entirely fabricated pseudo-pharmaceuticals [5]. There is no agreed-upon international definition of falsified or counterfeit medicines. The World Health Organisation (WHO) regards them as drugs that are “deliberately and fraudulently mislabelled with respect to identity and/or source” [6,7]. The European Medicines Agency (EMA) distinguishes between falsified medicines, as “fake medicines that are designed to mimic real medicines”, and counterfeit medicines,

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"medicines that do not comply with intellectual property rights" [8,9]. This lack of a consensus definition hinders discussions on this global health problem.

The consequences of falsified and counterfeit medicines extend beyond individual harm. They undermine public trust in healthcare systems, exacerbate drug resistance, compromise disease control efforts, and erode confidence in pharmaceutical supply chains [10–17]. This illegal trade places an onerous burden on regulatory authorities, law enforcement agencies, and public health institutions tasked with safeguarding the integrity of medicines.

The global nature of travel exposes travellers to unfamiliar healthcare systems and pharmaceutical markets [18,19], while the increased mobility of people across borders increases the risk of encountering counterfeit medications [20]. Travellers often lack an understanding of local healthcare landscapes, regulatory practices, and potential risks associated with obtaining medications abroad [21,22]. Despite the potentially severe consequences, travellers may not be adequately informed about these risks or equipped to navigate healthcare systems in foreign countries [23]. Travel health consultations play a crucial role in preparing individuals for the health-related challenges of international travel, including the risks associated with falsified and counterfeit medicines [24–26]. However, the adequacy and consistency of advice provided during these consultations can vary [27,28]. Increased awareness is crucial to empowering travellers to make informed decisions about their health and medications while abroad.

Beyond the immediate health risks, the trade in falsified and counterfeit medicines carries significant economic implications for individuals, healthcare systems, and governments [29]. This concern is amplified by the rise of pharmaceutical tourism, where travellers seek cheaper medications abroad, increasing their risk of encountering counterfeit drugs. The financial burdens on travellers can be substantial when substandard medications lead to treatment failures or additional medical expenses. With supply chains interconnected across borders, pharmaceuticals now traverse the globe at an unprecedented pace [30]. The intricate network of raw material suppliers, pharmaceutical manufacturers, and wholesale distributors has made it challenging to ensure the authenticity of pharmaceuticals throughout their journey from production to consumption. While this has facilitated timely access to medicines, it has also exposed vulnerabilities, enabling the spread of falsified and counterfeit medications. The advent of online pharmacies and digital transactions has provided convenience to travellers seeking medications abroad. However, it has also opened avenues for the illicit trade of falsified and counterfeit medicines [31,32]. Additionally, the use of advanced packaging and labelling technologies by counterfeiters adds complexity to identifying fraudulent products, posing specific challenges for travellers trying to ensure the authenticity of medications during their journeys [33].

While individual studies have illuminated aspects of this issue, a comprehensive examination of the cumulative knowledge base is lacking. This narrative review seeks to bridge this gap by evaluating relevant research, delineating the key themes, methodologies, and insights that collectively constitute the landscape of knowledge on falsified and counterfeit medicines in international travel. It aims to review the risks associated with counterfeit and falsified medications and identify knowledge gaps, areas of controversy, and avenues for future research that can contribute to a more robust understanding of this critical global health issue.

2. Materials and methods

This narrative review involved a comprehensive search of academic databases, including PubMed, MEDLINE, and Scopus, as well as relevant reports from international organisations such as the WHO, EMA, and INTERPOL, was undertaken. Diverse MeSH search terms were used to access all available literature on this subject (see Supplementary file). Sources were evaluated up to November 2023. Articles, reports, and studies spanning a wide range of disciplines, including pharmaceutical sciences, public health, law enforcement, and technology, were also included.

All reviewed literature was published in the English language. No date limitations were imposed on the search criteria; however, newer studies were prioritised. Grey literature, including reports, conference proceedings, and government publications, was also included to capture diverse perspectives and insights beyond peer-reviewed literature. Two of the three authors independently screened the literature to ensure thoroughness and accuracy.

Recognising the diversity in the types of counterfeit medicines, as well as the geographical patterns of their prevalence and the factors influencing their production, studies focusing on these aspects were included to uncover trends and variations in the risks posed by counterfeit medicines across different regions and drug categories. Given the frontline role of healthcare professionals in addressing pharmaceutical safety, a specific focus was placed on studies that explored their involvement, challenges, and contributions in detecting and preventing the spread of counterfeit medicines. This criterion was chosen to examine the interactions between healthcare practitioners and patients, and to understand the role of medical professionals in safeguarding public health, both domestically and internationally. Additionally, the inclusion criteria encompassed studies addressing the legal and regulatory aspects related to counterfeit and falsified medicines, aiming to provide a comprehensive overview of governance structures and challenges, and acknowledging the crucial role of regulatory authorities and legal frameworks in shaping pharmaceutical safety, particularly in the context of international travel. Furthermore, significant emphasis was placed on preventive efforts addressing interventions, campaigns, and collaborative initiatives aimed at combatting counterfeit medicines globally. This aspect explored diverse strategies implemented to safeguard public health during international travel, recognising the importance of proactive measures in mitigating the risks associated with falsified and counterfeit medicines.

To maintain a comprehensive and cohesive analysis, studies with a narrow scope that did not significantly contribute to the overarching themes of the review were excluded. Specifically, studies were excluded if they focused solely on a single case or instance of counterfeit medicine without broader implications, lacked sufficient data on geographical patterns or prevalence, or did not address the factors influencing the production of counterfeit medicines. Research limited to specific pharmaceutical compounds without consideration of the wider context of counterfeit medicines was also excluded to ensure the review covered a broad and diverse range of issues relevant to pharmaceutical safety on a global scale.

The data extraction process involved examination of each included study, with a focus on extracting information pertaining to the prevalence, types, and geographical patterns of falsified and counterfeit medicines encountered by international travellers. This information was synthesized to map the current global landscape and identify overarching trends and patterns. The narrative literature review utilised a thematic analysis approach to synthesise the findings, revealing commonalities and variations in literature.

While synthetizing the information, specific attention was directed toward identifying gaps in the current knowledge landscape related to falsified and counterfeit medicines. These gaps serve as signposts for the trajectory of subsequent research initiatives, potentially guiding scholars and practitioners toward areas that require deeper investigation.

3. Results

3.1. Therapeutic categories

The most prevalent of all falsified and counterfeit pharmaceuticals are antibiotics and antimicrobials, accounting for 28 % of the global

market in falsified and counterfeit medicines in 2012 [34]. This figure has increased in subsequent years, with antibiotic drugs accounting for 36 % of all counterfeit pharmaceuticals seized by customs worldwide in 2014–2016 [35]. A 2015 review found that the most commonly implicated antibiotics were beta-lactams, anti-folates, and cyclins [36]. Of the substandard medications studied, amoxicillin was reported in 29 countries, ampicillin was reported in 17 countries, tetracyclines were reported in 11 countries, and trimethoprim-sulfamethoxazole was reported in 10 countries [36]. This is consistent with earlier studies that found early generation antimicrobials, including penicillins and tetracyclines, to be the most commonly falsified and counterfeited [37]. It is important to note that Kelesidis & Falagas [36] used the term 'substandard' to describe medicines that do not meet quality standards. This distinction is important as 'substandard' refers to medicines that are authorised but fail to meet quality specifications, whereas 'falsified' and 'counterfeit' medicines involve intentional misrepresentation of identity, composition, or source. The distinction between these terms helps to clarify the different challenges posed by poor-quality medicines and the need for precise terminology in combating the issue of falsified and counterfeit medicines.

The risks associated with counterfeit antibiotics and antimicrobials are exacerbated during international travel in several critical ways. Travellers may encounter new or exotic environments during their journeys, exposing them to unfamiliar pathogens. The risk of contracting bacterial infections, including skin and soft tissue infections, traveller's diarrhoea or respiratory infections, is heightened. As a result, travellers may seek antibiotics or antimicrobials to manage these conditions, increasing the demand for these drugs abroad [38–42]. International travellers often resort to self-medication when faced with minor health issues, especially in regions where access to healthcare services may be limited or language barriers exist [43–45]. The ease of procuring antibiotics over the counter in some countries or obtaining them without a prescription contributes to the vulnerability of travellers to counterfeit drugs [46–50]. Travellers may unwittingly purchase counterfeit medications from local markets or pharmacies, believing them to be genuine [51,52]. The lack of familiarity with local pharmaceutical standards and counterfeiters' sophisticated mimicry of drug packaging exacerbates this risk [53]. Inadequate doses or incorrect formulations contribute to treatment failures, allowing bacterial infections to persist and potentially lead to the development of antibiotic resistance. This poses not only individual health risks but also carries wider population implications as drug-resistant infections become increasingly prevalent [54–56]. A survey of pharmacists working in healthcare settings in Nigeria found that 99.5 % associated counterfeit medicines with treatment failures, while 91.2 % believed that they contributed to antibiotic resistance [57]. This suggests that pharmacists are acutely aware of the problem, yet they face significant challenges in effectively addressing and mitigating the issue.

Falsified and counterfeit antimalarials and anti-infectives pose a significant threat to international travellers, particularly those visiting regions with a high incidence of infectious diseases [15,58–60]. Counterfeit cardiovascular drugs (e.g., antihypertensives, statins) and central nervous system medications (e.g., antidepressants and anxiolytics) are also frequently encountered. These drugs are likely chosen for counterfeiting due to the high incidence of conditions such as hypertension and depression. The lack of therapeutic efficacy or the presence of toxic substances contained in such drugs poses substantial risks to individuals managing chronic diseases [2,35,61–64]. Counterfeit vaccines jeopardise the immunity and health of patients. This is of concern to international travellers, many of whom may not seek vaccines before travel and seek to obtain them in developing countries. Such counterfeit vaccines can contribute to outbreaks of vaccine-preventable diseases, with far-reaching public health consequences for travellers and indigenous people [65–71]. Fig. 1 displays the relative value of seized falsified or counterfeit drug classes according to the Organisation for Economic Co-operation and Development (OECD).

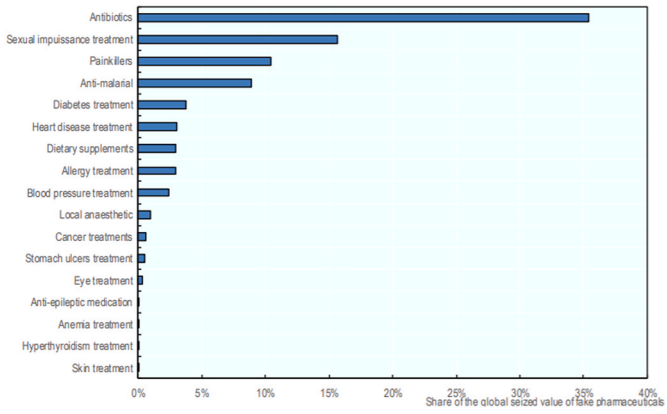

Fig. 1. Diversity of pharmaceutical agents among falsified medicines (Source: OECD, 2020).

3.2. Geographical distribution

While they are encountered in various parts of the world, specific countries and regions are more commonly associated with the production and distribution of illicit pharmaceuticals (Fig. 2). Although not major producers of medications, Southeast Asia, including countries such as Myanmar and Cambodia, has been identified as major sources of falsified and counterfeit drugs. The problem is not specific to any one nation but crosses borders, encompassing regional areas, with the Mekong of particular concern [72–77]. International travellers to Southeast Asia face unique challenges and risks related to falsified and counterfeit antimalarials and antibiotics, particularly when journeying to malaria-endemic regions [15,78,79]. Weak pharmaceutical regulations, porous borders, limited access to healthcare services contribute to the proliferation of counterfeit medications in this region with the potential to increase drug-resistant malaria [80–82].

The Sub-Saharan African region has been affected by a high incidence of infectious diseases, which has led to a significant demand for antimalarials, antibiotics, and antiretrovirals. As a result, falsified and counterfeit versions of these medications have proliferated [79,83,84]. Countries such as Nigeria, the Democratic Republic of the Congo (DRC), Tanzania, and Uganda have reported numerous cases of counterfeit pharmaceuticals [85–91]. A study between 2009 and 2015 of over 336, 000 antimalarial drugs in 49,500 medical outlets in eight African nations found, on average, that only 24 % of artemisinin-based

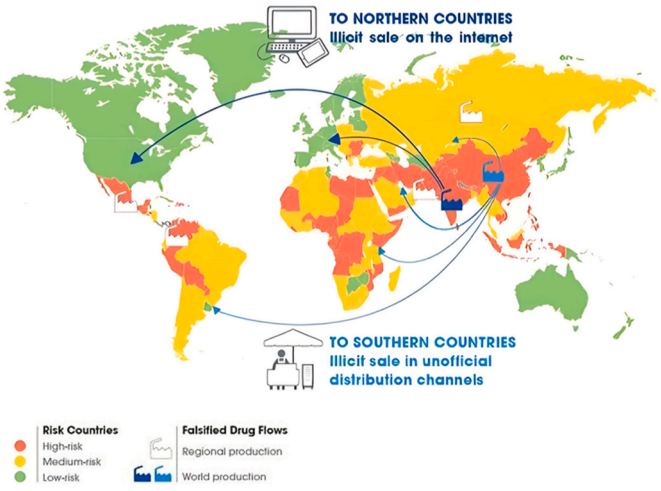

Fig. 2. Global distribution of falsified medicines (Source: https://healthpolicy-watch.news/fight-the-fakes-campaign-raises-awareness-of-falsified-substandard-medicines/).

combination therapy (ACT) drugs were quality-assured while 25 % were non-quality-assured. It was determined that the non-quality-assured drugs were predominantly available in private sector outlets and were infrequent (<10 %) within public sector settings. However, notable exceptions included the Democratic Republic of the Congo (DRC), where 39 % of non-quality-assured drugs were found in the public sector, and Zambia, where 85 % of such drugs were present in public sector settings. The relatively high proportion of non-quality-assured drugs in Zambia's public sector can be attributed to challenges in drug procurement and supply chain management, despite the presence of international donors. This situation contrasts with other contexts where low public sector availability of non-quality-assured drugs is more common, due to international aid and procurement processes that generally adhere to global quality-assurance standards [92]. Most falsified and counterfeit drugs in sub-Saharan Africa are imported from Asian countries, mainly India and China [92,93]. Several factors contribute to this problem in sub-Saharan Africa, including inadequate healthcare infrastructure, regulatory challenges, limited access to quality medicines, and the high cost of genuine medicines, all of which make it easier for counterfeit drugs to infiltrate the market [94–96].

The majority (54 %) of falsified and counterfeit drugs reported worldwide in 2006 were manufactured in India [97]. A more recent study puts that number at 75 % [98]. Illicit manufacturers within India predominantly produce substandard or counterfeit versions of generic medications, which can then enter the global pharmaceutical supply chain [99–101]. A study of falsified medicines in Myanmar found that 75.8 % of the medicines being sold in pharmacies in Mandalay were of Indian origin, and 20.5 % were found to be either substandard or falsified [73]. India's complex pharmaceutical landscape, with its mixture of highly reputable manufacturers and unregulated production units, makes it a challenging environment to monitor and regulate [102,103]. The high cost of medicines, limited access to medical care, and a lack of knowledge amongst the general population were highlighted as key factors influencing the sale of falsified and counterfeit medicines in India [104].

In 2006, China and Hong Kong were responsible for 31 % of falsified and counterfeit medications worldwide [97]. This issue affects many drugs from antibiotics to lifestyle medications and even vaccines. The country's expansive pharmaceutical manufacturing industry, coupled with the presence of unregulated and often clandestine production facilities, creates opportunities for counterfeiters [49,105,106].

Eastern European countries, including Russia, have also been associated with falsified and counterfeit pharmaceuticals, particularly lifestyle medications and antibiotics [107–112]. The WHO estimates that in former Soviet countries the incidence of counterfeit pharmaceuticals may be as high as 20 % [36]. Weak regulatory oversight, as well as corruption, has contributed to the prevalence of falsified and counterfeit drugs in these regions. Counterfeit pharmaceuticals, originating from within the region or imported from other sources, can enter both domestic and international markets [113,114].

In Latin America, countries such as Brazil, Chile and Peru have encountered issues with falsified and counterfeit medicines. Counterfeit pharmaceuticals in this region encompass lifestyle medications, antibiotics, antiretrovirals and analgesics [115,116]. Factors such as economic disparities, lax regulatory enforcement, corruption, and porous borders have contributed to the presence of falsified and counterfeit drugs [50,114,117].

The internet and transnational criminal networks play a pivotal role in the distribution of adulterated and low-quality drugs, often sold illegally and without the need for prescriptions [118,119]. These criminal networks often operate across borders, making it challenging to pinpoint a single geographical location as the source of the problem. The internet has facilitated the sale of counterfeit drugs to a global audience, bypassing traditional supply chains and regulatory oversight [51,120]. Almost 25 % of U.S. adults purchased prescription medicines online in 2017, with 20 % of purchases made via websites without any link to local healthcare professionals. It was also found that 96 % of online pharmacies operating in the U.S. did so without any regulatory oversight or adherence to pharmaceutical standards [121]. Despite the risks, individuals use online pharmacies for reasons such as convenience and lower cost compared to drugs sourced from licensed sellers [122]. Many countries currently lack legislation regulating the operation of online pharmacies [123]. The most common locations of online pharmacies appear to be the U.S., Canada and the U.K [124]. Of 44 sites selling Viagra® online in the U.K. in 2010, only 56.8 % provided an email address and 47.7 % supplied a postal address [125]. The high proportion of online pharmacies without a physical address or contact email could make it difficult to ascertain the location and legitimacy of the online pharmacy. Furthermore, the addresses provided may have consisted of P.O. boxes or non-physical addresses, adding to the complexity of the issue and making it easier for fraudulent operators to avoid detection and regulation.

While North America generally has robust regulatory frameworks and strong healthcare systems, there are still considerations for travellers. The ease of online purchasing in North America can expose travellers to falsified and counterfeit drugs. Travellers in North America relying on such sources may inadvertently encounter falsified or counterfeit antimalarials and antibiotics [126]. Travellers may not be familiar with the regulatory frameworks regarding the importation of medications in North America. Attempting to bring medications into the region without proper documentation or adherence to regulatory standards may have legal implications. International travellers may face legal consequences if found in possession of falsified or counterfeit medications, even if purchased unknowingly, disrupting travel plans and leading to potential consequences for travellers who unintentionally acquire counterfeit drugs [127].

In 2012, the U.S. Food and Drug Administration (FDA) uncovered a sophisticated operation involving the distribution of counterfeit Avastin®, a widely used cancer medication. The falsely labelled drugs were distributed to multiple healthcare providers across the United States. This incident raised serious concerns about the integrity of the pharmaceutical supply chain and the potential harm posed to patients relying on genuine medications for life-threatening conditions [128]. The incident highlighted the advanced tactics employed by counterfeiters to infiltrate the pharmaceutical distribution network of a high-income, developed nation. The drugs closely mimicked the appearance of the genuine drug, making visual identification unreliable for healthcare professionals. This underscored the vulnerability of the U.S. healthcare system to fraudulent activities, prompting increased scrutiny of supply chain security and regulatory measures in the years since [129].

The prevalence of counterfeit prescription drugs extends beyond the borders of the USA. A recent study, conducted from 2018 to 2022, investigating the presence of counterfeit prescription drugs in Northern Mexico, particularly in pharmacies catering to English-speaking tourists, revealed that 70 % of pharmacies provided controlled substances without a prescription, and 27.5 % dispensed counterfeit medications. The high rate of pharmacies dispensing controlled substances without a prescription suggests a lack of regulatory oversight, which can correlate with a higher risk of counterfeit medications being distributed. Samples labelled as "Adderall" often contained methamphetamine, while those labelled as "Oxycodone" frequently contained fentanyl or heroin [130]. This highlights the public health risk posed by the availability of counterfeit medications in tourist-oriented pharmacies and emphasises the need for increased surveillance and awareness amongst international travellers due to Mexico's limited infrastructure for drug monitoring.

While the European Union (EU), like the U.S., maintains a high standard of pharmaceutical regulations and healthcare infrastructure, international travellers to Europe may still encounter risks related to counterfeit and falsified medications. In some European countries it is possible to buy certain medications, including antibiotics, without requiring a prescription [47]. The absence of prescription requirements can lead to an increased risk of self-treatment, potentially exposing

travellers to substandard or inappropriate use of medications, as pharmacies operating under less stringent regulatory oversight are more vulnerable to infiltrations by counterfeit drugs, as they may not adhere to the same rigorous standards for sourcing and verifying the authenticity of their medications. This combination of factors can contribute to the presence of falsified medications in the market. Likewise, akin to North America, the ease of purchasing medications online poses a unique risk for travellers to Europe, exposing them to the risk of receiving counterfeit or substandard drugs from less reputable sources [131–133]. Fig. 3 illustrates the regional frequency of counterfeit pharmaceutical seizures by law enforcement agencies.

3.3. Considerations for international travellers

Annually, an estimated 25–30 million international travellers visit regions of Southeast Asia and Sub-Saharan Africa where malaria is endemic [134]. An estimated 30,000 malaria infections occur annually amongst travellers [135]. A GeoSentinel analysis between 2003 and 2016 found that 83 % of patients diagnosed with malaria post-travel had been exposed in sub-Saharan Africa [136]. This indicates the need for authentic antimalarial drugs available both for preventive and treatment abroad. However, as falsified and counterfeit antimalarials are prevalent in these regions, travellers can unknowingly purchase and consume counterfeit antimalarials, increasing the risk of contracting malaria [79,96,137–139].

Sub-Saharan Africa, as well as parts of Asia, bear a substantial burden of infectious diseases, including malaria, HIV/AIDS, and various bacterial infections [140–143]. International travellers to this region often require antimalarials, antiretrovirals, and antibiotics. The high demand for these medications creates an environment where falsified and counterfeit drugs can infiltrate the market. In remote and less-developed parts of Asia and Sub-Saharan Africa, travellers may have limited access to high quality healthcare facilities [104]. This can lead to increased reliance on local unregulated pharmacies or informal drug vendors, where the risk of encountering counterfeit medications is much higher. Without access to medical professionals or reliable sources, travellers are more susceptible to obtaining falsified and counterfeit medications [144].

The distribution networks for counterfeit medications often transcend national borders. Falsified and counterfeit drugs originating from Asian countries, including India and China, have been detected in international markets, highlighting the global nature of the falsified and counterfeit medicine trade and the need for a standardized drug pedigree system [145,146]. Travellers may inadvertently come into contact with these falsified and counterfeit medications when purchasing pharmaceuticals during their journeys abroad. Due to the high cost of prescription medications in countries such as the United States and Canada, travellers from these countries might be inclined to purchase medications abroad to save money [147], potentially increasing their risk of encountering falsified and counterfeit medications.

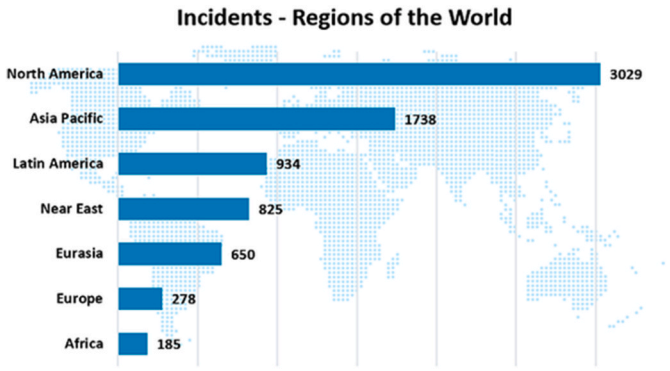

Fig. 3. Global incidence of falsified medicines (Source: https://www.psi-inc.org/geographic-distribution).

3.4. Production of falsified and counterfeit medicines

Ensuring precise strength and purity of drugs is an essential part of any drug manufacturing process and is usually maintained by careful monitoring of manufacturing operations and procedures. Drug manufacturers must operate in accordance with good manufacturing practices (GMP) to maintain the efficacy, quality, and safety of pharmaceuticals [148–151]. Falsified and counterfeit drugs typically deviate from GMPs in several critical ways by deliberately or inadvertently violating these regulations [152,153]. This can result in medications that do not conform to global standards, putting patients' health at risk. For international travellers, the ability to identify falsified and counterfeit medicines poses many challenges. Examination of the product packaging and label can provide clues about the authenticity of a medication [126]. Key indicators of counterfeit drugs include discrepancies in packaging design, missing or incorrect labelling information, and unusual or inconsistent fonts and colours. Additionally, counterfeit tablets can often have a chalky appearance or taste [154]. For travellers and healthcare providers, being aware of these signs can aid in identifying potentially counterfeit medications. Table 1 summarises the key deviations from normal drug manufacturing practices, which can help in recognising counterfeit products. For a more comprehensive approach, travellers should consider purchasing medications from reputable sources and consult local guidelines on medication authenticity. Providers should educate patients on these signs and encourage vigilance when obtaining medications from less familiar or non-traditional sources.

3.5. Role of healthcare professionals

Pharmacists play a crucial role in combating the issue of falsified and counterfeit medications. Their expertise, accessibility, and direct interaction with patients make them frontline healthcare professionals who can contribute significantly to safeguarding public health in both domestic and international settings [152]. Pharmacists should be trained to verify the authenticity of pharmaceutical products. Before patients purchase medications, pharmacists can examine the packaging, labelling, and security features to identify potential signs of counterfeit drugs. Suspicious products can then be reported to regulatory authorities for further investigation and not dispensed to a patient [184].

A survey of Egyptian pharmacists found that 70.3 % felt confident in their ability to visually determine if a medicine was falsified and counterfeit. Elements of authenticity they examined included product-specific authentication markings (69.9 %), shape (53.6 %), embossing (24.4 %), colour (17.1 %) and packaging (14.6 %). 84 % stated that their awareness was due to previous encounters with falsified and counterfeit medications, while 35 % relied on information from pharmaceutical inspectors and other pharmacists; surprisingly 95.4 % had never had any professional training on the detection of falsified and counterfeit medicine and 82.9 % felt their current knowledge and skills were limited or inadequate. Just over half (53.1 %) of respondents had awareness of drug authentication techniques designed to prevent counterfeiting, with the most widely recognised being a digital watermark [185].

Pharmacists are in a unique position to educate patients about the risks associated with falsified and counterfeit medications. They can inform patients about the importance of obtaining medications from reputable sources, the potential dangers of online pharmacies, and the need to report any unusual effects or packaging irregularities [186]. However, findings from Sudan suggest that without addressing the underlying factors that drive consumers to buy falsified and counterfeit medications, such as high cost of branded drugs, educational efforts may prove ineffective if inexpensive viable alternatives are not available [187]. While these findings are based on the specific context of Sudan, similar challenges related to drug affordability and access may be

Table 1
Deviation from good manufacturing practices.

Aspect	Description	References
Poor quality ingredients	Active ingredients: Falsified and counterfeit drugs often contain substandard or insufficient active ingredients, leading to ineffective treatment.	[155–158]
	Inactive ingredients: Excipients and fillers in falsified drugs may be of lower quality or contaminated, compromising drug safety.	[159,160]
Inadequate formulation and manufacturing	Formulation: Incorrect formulations in counterfeit drugs can result in inconsistent drug release and potential adverse effects.	[159,161]
	Manufacturing conditions: Falsified drugs are often produced in substandard facilities lacking proper equipment and adherence to good manufacturing practices (GMP), leading to contamination and errors.	[162,163]
Lack of quality control	Quality control procedures: Counterfeit drug producers typically lack adequate quality control measures, resulting in inconsistent product quality.	[90, 164–166]
	Batch testing: Falsified drugs often skip batch testing, leading to variations in quality between batches.	[167]
Packaging and labelling irregularities	Authentication features: Counterfeit drugs lack, or attempt to replicate with lower precision, security features including holographic seals, tamper-evident packaging, or unique identifiers present in genuine pharmaceuticals.	[168–171]
	Information accuracy: Falsified drugs may contain inaccurate information on packaging and labelling, such as false expiration dates or dosage instructions.	[155, 172–174]
Traceability and documentation	Documentation: Counterfeit drug manufacturers often lack proper documentation or provide fraudulent records.	[175–177]
	Traceability: Falsified drugs are often untraceable, making it challenging to identify their source or movement in the supply chain.	[175,176, 178,179]
Compliance with regulatory standards	Regulatory approvals: Counterfeit drugs lack necessary regulatory approvals and are often illegally produced and distributed.	[116,180, 181]
	Quality audits: Counterfeit drug producers operate outside regulatory inspections, avoiding scrutiny of their manufacturing processes.	[175,182, 183]

applicable in other countries with comparable economic and healthcare conditions. Therefore, while the exact dynamics may vary, the principle that access to affordable, quality medications is crucial for the effectiveness of educational efforts is likely relevant in a broader context.

In a pre-travel consultation, healthcare professionals provide recommendations and guidance to travellers to determine potential health risks, educate on methods of prevention, and provide immunisations and medication for preventable diseases. This helps to ensure their health and safety during international trips [188]. However, existing literature on pre-travel consultations often lacks specific guidance concerning counterfeit or falsified medicines, primarily referencing them only in the context of chemoprophylaxis. The CDC Yellow Book addresses the issue of counterfeit medicines in the context of the pre-travel consultation. Recommendations include purchasing medications domestically before departure, ensuring medicines remain in their original packaging, buying from legitimate pharmacies, avoiding suspiciously low-priced medications, being familiar with packaging details, and reporting any suspected counterfeit products to www.who.int/medicines/services/counterfeit/report/en/.[19,189]. The CDC also provides some best practices for travellers who must acquire medications abroad (https://wwwnc.cdc.gov/travel/page/counterfeit-medicine#:~:text=If_20possible_2C_20bring_20your_20medicine,File%20Formats%20Help)

In addition to the frontline role pharmacists play in combating falsified and counterfeit medicines, the importance of equipping healthcare professionals with robust, up-to-date resources cannot be overstated. The complexity of navigating international pharmaceutical regulations, particularly for travellers, underscores the need for comprehensive databases that provide current information on medication legality, availability, and alternatives across different countries. As highlighted in Shmorgun et al. [4], the development of a database designed to aid healthcare providers in offering accurate pre-travel advice is critical in ensuring that patients receive the correct medications, even when travelling across borders. These databases would not only support pharmacists in verifying the authenticity of pharmaceuticals but also empower them to advise on legal and safe alternatives when specific medications cannot be carried abroad. As international travel continues to rise, the role of these informational resources will become increasingly vital in safeguarding public health against the risks posed by falsified and counterfeit medications. This approach can complement the educational efforts of healthcare professionals, ensuring their ability to provide well-rounded, informed guidance to travellers, ultimately reducing the risks associated with cross-border pharmaceutical transactions.

3.6. Legal and regulatory aspects

Regulatory authorities and legal frameworks play a significant role in preventing the production, distribution, and sale of medications that fall short of international quality, safety, and efficacy standards. Most nations have a national regulatory authority which oversees the safety, efficacy, and quality of pharmaceutical products within their respective countries [190]. Their responsibilities include evaluating applications for the registration and approval of pharmaceutical products, ensuring compliance with GMP standards, market surveillance, quality control and testing, the education of healthcare professionals and the public, collaboration with international regulatory bodies such as the WHO, and the legal enforcement of pharmaceutical regulations [191].

The quality of national regulatory authorities can vary significantly from one country to another. It is estimated that, globally, at least 30 % of national regulatory authorities face challenges in executing their essential regulatory functions [192]. Most regulatory authorities in low-income countries lack the necessary infrastructure to ensure the quality, efficacy, and safety of pharmaceuticals [193]. Many developing nations also lack a well-established regulatory framework capable of effectively targeting criminal networks [90]. A WHO report found that 90 % of regulatory authorities in sub-Saharan Africa had limited capacity to perform their core regulatory functions. A notable exception was South Africa. As a result, many nations often depend on regulatory agencies in more developed, high-income, countries known for their consistent and rigorous evaluation capabilities pertaining to medicine registration [191,194].

A shortage of adequately qualified assessors and inspectors was a widespread issue in 92 % of countries in the WHO report, which also emphasised the necessity for specific training in current GMP. Overall, national regulatory authorities were not in line with recommended WHO standards [191]. This situation puts the lives of both citizens of, and travellers to, low-income countries at risk. Although there is agreement that many national regulatory authorities are understaffed, the prevailing literature often falls short of recording specific employment statistics, the level of existing regulatory expertise, or the ideal number of qualified professionals needed for optimal efficiency in these organisations. It is imperative to quantify the depth of regulatory expertise within Africa, particularly considering the substantial

investments made by international development partners in training regulatory professionals [192].

Global leadership in the area is decentralised and split between several key international organisations including the WHO, the United Nations Office on Drugs and Crime (UNODC), INTERPOL and the World Customs Organisation (WCO); separate organisations, each with a diverse range of responsibilities, goals and enforcement capabilities [195]. The WHO has repeatedly passed resolutions and guidance focusing on shaping policy, especially through the supervision of initiatives and programs within individual countries [196]. It is important to recognise, however, that the WHO lacks enforcement powers and is not equipped to deal directly with criminal or law enforcement matters, which hinders its ability to effectively respond to crimes relating to falsified and counterfeit medicines [197]. The UNODC has made recent endeavours to promote international collaboration in combating falsified and counterfeit medicines. One suggestion involves establishing a trilateral coalition comprising the WHO, UNODC, and INTERPOL [197].

Ultimately, an international convention against falsified and counterfeit medicines is an essential first step to harmonise regulation and enforcement in a global context, offering a legal foundation that is currently absent. Key aspects would include: the introduction of an agreed upon international definition of what constitutes a counterfeit or falsified medication, thereby avoiding the contradicting perspectives caused by varying and vague terminology used today; the implementation of domestic laws that criminalise the production, trafficking, and distribution of falsified and counterfeit medicines, as per the aforementioned definitions, enabling the prosecution and extradition of individuals involved in these activities; the implementation of a legal and institutional framework through which standards could be continually refined; and a guarantee of financial and technical support through local and regional networks, with particular emphasis on lower-income countries, the objective being to empower these nations to bolster their national regulatory authorities to a degree whereby they can reliably ensure patients' access to high-quality medicines [198].

The European Falsified Medicines Directive (FMD) came into effect on February 9, 2019. It is a comprehensive regulatory framework established by the EU to combat the circulation of counterfeit or falsified medicines within the European pharmaceutical market. The primary goal of the FMD is to ensure the safety and authenticity of medicines for patients across the EU [9]. The FMD introduces several crucial provisions to safeguard the pharmaceutical supply chain or pedigree. It mandates the serialisation of prescription medications, necessitating manufacturers to include unique identifiers and anti-tampering devices on medicine packages, enabling tracking and authentication during distribution. The directive establishes national repositories to store data from these unique identifiers, which pharmacists and authorised individuals can access to verify the authenticity of medicinal products before dispensing them to patients. It also emphasises the use of safety features, such as anti-tampering devices, to prevent unauthorised access to medicine packages [199]. Moreover, the FMD assigns specific responsibilities to various stakeholders within the pharmaceutical supply chain, including manufacturers, wholesalers, and pharmacies, requiring them to maintain secure and compliant medicine movement through licensing and adherence to standardized procedures [200].

4. Discussion

Falsified and counterfeit medicines represent a substantial challenge in the realm of international travel and public health. They encompass a wide range of products, from lifestyle medications to life-saving drugs. The global nature of travel exposes individuals to unfamiliar healthcare systems and pharmaceutical markets. They may encounter counterfeit medications during their journeys, often unknowingly. This issue is not confined to a specific geographic region; it spans the globe, affecting both high-income and low-income countries. Travellers from high-income nations may unknowingly purchase counterfeit drugs while abroad, while those from low-income countries may be more vulnerable due to the lack of education, robust regulatory measures and the prevalence of substandard pharmaceuticals.

The manufacture of falsified and counterfeit medicines is a multifaceted process that deviates from GMP [153]. The current literature highlights the use of poor-quality ingredients [155,156], incorrect formulations [19], and a lack of quality control measures [90]. Travellers can be exposed when they purchase medications abroad, particularly from sources such as unregulated local pharmacies or online vendors [111,201]. Pharmacists may be equipped to verify the authenticity of pharmaceutical products, but research reveals that there is a need for greater awareness, training, and resources to enhance their capabilities [184–186]. Moreover, the literature underscores the importance of patient education and pre-travel consultations to mitigate the risks associated with counterfeit medicines.

The legal and regulatory aspects are pivotal in addressing this issue. Travellers may find themselves in countries with varying degrees of regulatory oversight and quality control measures. While most nations have national regulatory authorities overseeing pharmaceutical products, the quality of these authorities varies significantly [192]. Many low- and middle-income countries face challenges in executing their regulatory functions, emphasising the need for capacity building [90,191,193]. The development of an agreed-upon international definition of falsified and counterfeit medicines, implementation of domestic laws, and the provision of financial and technical support to lower-income countries are critical components of this framework [198].

Efforts to combat falsified and counterfeit medicines involve a multitude of international organisations, including the WHO, the UNODC, INTERPOL, and the WCO. Research has highlighted the successes of global operations like INTERPOL's Operation Pangea and the WCO's STOP initiatives in seizing counterfeit drugs and disrupting criminal networks [202–205]. However, these organisations have been challenged by issues of funding and the complexities of coordinating their roles and responsibilities.

The current literature offers valuable insights into falsified and counterfeit medicines, but research gaps remain. Future studies should explore the human and societal impact, the role of online pharmacies, the dynamics of global collaboration, the efficacy of emerging technologies, and strategies to enhance consumer awareness. Furthermore, specific travel-related research can explore the experiences of travellers encountering counterfeit medicines and the role of international travel in the spread of falsified and counterfeit drugs. Addressing these gaps is critical for developing more comprehensive strategies to safeguard public health, ensure the integrity of the pharmaceutical supply chain, and develop more robust strategies to protect travellers from falsified and counterfeit medicines and ensure their health and safety during international journeys.

While this is the first comprehensive review of the literature on falsified and counterfeit drugs, it is subject to some limitations. The literature search was restricted to publications in the English language which may have caused some important sources to be overlooked. Although three databases were interrogated, it is possible that additional material would have been provided by a search of other databases, including Embase and PharmaPendium.

5. Conclusions

International travellers face unique risks related to falsified and counterfeit medicines, highlighting the critical importance of this issue in the context of global travel. As individuals explore different parts of the world, they encounter diverse healthcare systems and pharmaceutical markets, making them more susceptible to counterfeit medications. Tackling this complex challenge requires collaborative efforts from healthcare professionals, regulatory authorities, and international organisations. It also necessitates ongoing research to further understand the nuances of this issue and to develop effective strategies to protect

patients and the pharmaceutical supply chain.

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Ethical considerations

His research did not involve human or animal subjects or original data and was therefore not subject to ethics committee approval.

Data availability

Data sharing is not applicable to this article as no new data were created or analysed in this study.

CRediT authorship contribution statement

Aonghus J. Feeney: Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation, Conceptualization. **Jeffery A. Goad:** Writing – review & editing, Validation, Supervision, Investigation, Data curation. **Gerard T. Flaherty:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tmaid.2024.102758.

References

[1] Bakker-'t Hart IME, Ohana D, Venhuis BJ. Current challenges in the detection and analysis of falsified medicines. J Pharm Biomed Anal 2021;197:113948.
[2] Ziavrou KS, Noguera S, Boumba VA. Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic. Forensic Sci Int 2022;338:111382.
[3] Fantasia HC, Vooys KM. Public health implications of counterfeit medications. Nurs Womens Health 2018;22(3):264–8.
[4] Shmorgun A, Mészáros Á, Felkai P. Cross-border medicines-database for professionals who provide pre-travel advice. Orv Hetil 2024;165(20):769–74.
[5] Sirrs CJ, Fakes Fluid, Counterfeits Contested. The world health organization's engagement with fake drugs, 1948–2017. Medicine Anthropology Theory 2023;10(3):1–29.
[6] O'Hagan A, Garlington A. Counterfeit drugs and the online pharmaceutical trade, a threat to public safety. Forensic Research & Criminology International Journal 2018;6(3):151–8.
[7] WHO. Counterfeit drugs: guidelines for the development of measures to combat counterfeit drugs. World Health Organization; 1999.
[8] Frontini R. Falsified Medicines Directive: are we heading in the right direction? London, England. p. maapoc: SAGE Publications Sage UK; 2017, 0000011.
[9] European Commission. Falsified medicines. https://health.ec.europa.eu/medicinal-products/falsified-medicines_en; 2023 Oct 2023 Oct 25 2023.
[10] Lima MBA, Yonamine M. Counterfeit medicines: relevance, consequences and strategies to combat the global crisis. Brazilian Journal of Pharmaceutical Sciences 2023;59:e20402.
[11] Akinyandenu O. Counterfeit drugs in Nigeria: a threat to public health. African journal of pharmacy and pharmacology 2013;7(36):2571–6.
[12] Seiter A. Health and economic consequences of counterfeit drugs. Clin Pharmacol Ther 2009;85(6):576–8.
[13] Cockburn R, Newton PN, Agyarko EK, Akunyili D, White NJ. The global threat of counterfeit drugs: why industry and governments must communicate the dangers. PLoS Med 2005;2(4):e100.
[14] Sholy LB. Nature, extent, awareness, and attitudes towards counterfeit medicine in Lebanon. University of Brighton Brighton; 2015.
[15] Dondorp A, Newton P, Mayxay M, Van Damme W, Smithuis F, Yeung S, Petit A, Lynam A, Johnson A, Hien T. Fake antimalarials in Southeast Asia are a major impediment to malaria control: multinational cross-sectional survey on the prevalence of fake antimalarials. Trop Med Int Health 2004;9(12):1241–6.
[16] Newton PN, Green MD, Fernández FM, Day NP, White NJ. Counterfeit anti-infective drugs. Lancet Infect Dis 2006;6(9):602–13.
[17] Sholy L, Saliba C. Public awareness, experiences and views about counterfeit medicines in Lebanon. J Pharmaceut Health Serv Res 2018;9(2):161–9.
[18] Johns Hopkins Medicine. Emerg Infect Dis 2023 Oct 18 2023. Available from: https://www.hopkinsmedicine.org/health/conditions-and-diseases/emerging-infectious-diseases.
[19] Hagmann S. Obtaining health care abroad: CDC Yellow Book 2024. https://wwwnc.cdc.gov/travel/yellowbook/2024/health-care-abroad/health-care-abroad/avoiding-poorly-regulated-medicines-and-medical-products; 2023 Oct 14 2023.
[20] NHS. Travelling abroad for medical treatment. https://www.fitfortravel.nhs.uk/advice/general-travel-health-advice/travelling-abroad-for-medical-treatment; 2023.
[21] Crooks VA, Turner L, Cohen IG, Bristeir J, Snyder J, Casey V, Whitmore R. Ethical and legal implications of the risks of medical tourism for patients: a qualitative study of Canadian health and safety representatives' perspectives. BMJ Open 2013;3(2):e002302.
[22] Chen YB, Flood CM. Medical tourism's impact on health care equity and access in low-and middle-income countries: making the case for regulation. J Law Med Ethics 2013;41(1):286–300.
[23] Kain D, Findlater A, Lightfoot D, Maxim T, Kraemer MU, Brady OJ, Watts A, Khan K, Bogoch II. Factors affecting pre-travel health seeking behaviour and adherence to pre-travel health advice: a systematic review. J Trav Med 2019;26(6):taz059.
[24] Carroll B, Daniel A, Behrens RH. Travel health. Part 1: preparing the tropical traveler. Br J Nurs 2008;17(16):1046–51.
[25] Torresi J, McGuinness S, Leder K, O'Brien D, Ruff T, Starr M, Gibney K, Torresi J, McGuinness S, Leder K. Principles of pre-travel healthcare. Manual of Travel Medicine; 2019. p. 1–17.
[26] Akunyili D. Fake and counterfeit drugs in the health sector: the role of medical doctors. Ann Ib Postgrad Med 2004;2(2):19–23.
[27] Al-Dahshan A, Selim N, Al-Kubaisi N, Mahfoud Z, Kehyayan V. Scope and predictors of travel medicine practice among primary care physicians in Qatar. Preventive Medicine Reports 2023;35:102337.
[28] Hatz C, Chen LH. Pretravel consultation. In: Travel medicine E-book. Elsevier; 2019. p. 25–30.
[29] Blackstone EA, Fuhr Jr JP, Pociask S. The health and economic effects of counterfeit drugs. American health & drug benefits 2014;7(4):216.
[30] Walker N. Impacts of glocalization on the pharmaceutical industry. https://www.pharmasalmanac.com/articles/impacts-of-glocalization-on-the-pharmaceutical-industry; 2019 Oct 2023.
[31] Thalkari AB, Karwa PN, Gawli CS. A review on online pharmacy: views and counterviews. Asian Journal of Pharmacy and Technology 2018;8(2):108–11.
[32] deKieffer DE. The internet and the globalization of counterfeit drugs. J Pharm Pract 2006;19(3):171–7.
[33] Dégardin K, Guillemain A, Klespe P, Hindelang F, Zurbach R, Roggo Y. Packaging analysis of counterfeit medicines. Forensic Sci Int 2018;291:144–57.
[34] Delepierre A, Gayot A, Carpentier A. Update on counterfeit antibiotics worldwide; public health risks. Med Maladies Infect 2012;42(6):247–55.
[35] OECD/EUIPO. In: Trade Illicit, editor. Trade in counterfeit pharmaceutical products. OECD Publishing Paris; 2020.
[36] Kelesidis T, Falagas ME. Substandard/counterfeit antimicrobial drugs. Clin Microbiol Rev 2015;28(2):443–64.
[37] Wondemagegnehu E. *Counterfeit and substandard drugs in Myanmar and Viet Nam.* WHO Report. WHO/EDM/QSM; 1999. p. 99.
[38] Harvey K, Esposito DH, Han P, Kozarsky P, Freedman DO, Plier DA, Sotir MJ. Surveillance for travel-related disease—GeoSentinel surveillance system, United States, 1997–2011. Morb Mortal Wkly Rep - Surveillance Summ 2013;62(3):1–23.
[39] Angelo KM, Kozarsky PE, Ryan ET, Chen LH, Sotir MJ. What proportion of international travellers acquire a travel-related illness? A review of the literature. J Trav Med 2017;24(5):46.
[40] Michal Stevens A, Esposito DH, Stoney RJ, Hamer DH, Flores-Figueroa J, Bottieau E, Connor BA, Gkrania-Klotsas E, Goorhuis A, Hynes NA. Clostridium difficile infection in returning travellers. J Trav Med 2017;24(3):taw099.
[41] Hill DR. Health problems in a large cohort of Americans traveling to developing countries. J Trav Med 2000;7(5):259–66.
[42] Stoney RJ, Esposito DH, Kozarsky P, Hamer DH, Grobusch MP, Gkrania-Klotsas E, Libman M, Gautret P, Lim PL, Leder K, Schwartz E, Sotir MJ, Licitra C, Network GS. Infectious diseases acquired by international travellers visiting the USA†. J Trav Med 2018;25(1).
[43] Gandhi AR, Rao SR, Chen LH, Nelson MD, Ryan ET, LaRocque RC, Hyle EP. Prescribing patterns of antibiotics for the self-treatment of travelers' diarrhea in Global TravEpiNet, 2009–2018. In: Open forum infectious diseases. Oxford University Press US; 2020.
[44] Diemert DJ. Prevention and self-treatment of traveler's diarrhea. Clin Microbiol Rev 2006;19(3):583–94.
[45] d Ericsson C. Traveler's diarrhea: prevention and self-treatment. The travel and tropical medicine manual E-book. 2016. p. 112.
[46] Munthe C, Malmqvist E, Rönnerstrand B. Non-prescription acquisition of antibiotics: prevalence, motives, pathways and explanatory factors in the Swedish population. PLoS One 2022;17(9):e0273117.
[47] Gravningen K, Field N, Blix HS, Asfeldt AM, Småbrekke L. Non-prescription purchase of antibiotics during travel abroad among a general adult population in

Norway: findings from the seventh Tromsø Study. PLoS One 2020;15(2):e0228792.
[48] Sono TM, Yeika E, Cook A, Kalungia A, Opanga SA, Acolatse JEE, Sefah IA, Jelić AG, Campbell S, Lorenzetti G. Current rates of purchasing of antibiotics without a prescription across sub-saharan Africa; rationale and potential programmes to reduce inappropriate dispensing and resistance. Expert Rev Anti-infect Ther 2023.
[49] Pan H, Luo H, Chen S, Ba-Thein W. Pharmacopoeial quality of antimicrobial drugs in southern China. Lancet Global Health 2016;4(5):e300–2.
[50] Husaini DC, Bolon F, Smith N, Reynolds R, Humes S, Cayetano V. Quality of medicines and public health in Latin America and the Caribbean (LAC): a review. Int J Pharmaceut Healthc Market 2023.
[51] Siva N. Tackling the booming trade in counterfeit drugs. Lancet 2010;376(9754):1725–6.
[52] Cheng MM. Is the drugstore safe? Counterfeit diabetes products on the shelves. J Diabetes Sci Technol 2009;3(6):1516–20.
[53] Chikowe I, Bliese SL, Lucas S, Lieberman M. Amoxicillin quality and selling practices in urban pharmacies and drug stores of Blantyre, Malawi. Am J Trop Med Hyg 2018;99(1):233.
[54] Nickerson JW, Attaran A, Westerberg BD, Curtis S, Overton S, Mayer P. Fatal bacterial meningitis possibly associated with substandard ceftriaxone—Uganda. MMWR (Morb Mortal Wkly Rep) 2013;64(50 & 51):1375–7. 2016.
[55] Kelesidis T, Kelesidis I, Rafailidis PI, Falagas ME. Counterfeit or substandard antimicrobial drugs: a review of the scientific evidence. J Antimicrob Chemother 2007;60(2):214–36.
[56] Taylor R, Shakoor O, Behrens R. Drug quality, a contributor to drug resistance? Lancet 1995;346(8967):122.
[57] Adigwe OP, Onavbavba G, Wilson DO-m. Challenges associated with addressing counterfeit medicines in Nigeria: an exploration of pharmacists' knowledge, practices, and perceptions. Integrated Pharm Res Pract 2022:177–86.
[58] Lon C, Tsuyuoka R, Phanouvong S, Nivanna N, Socheat D, Sokhan C, Blum N, Christophel E, Smine A. Counterfeit and substandard antimalarial drugs in Cambodia. Trans R Soc Trop Med Hyg 2006;100(11):1019–24.
[59] Yong YL, Plançon A, Lau YH, Hostetler DM, Fernández FM, Green MD, Sounvoravong S, Nara S, Boravann M, Dumrong T. Collaborative health and enforcement operations on the quality of antimalarials and antibiotics in southeast Asia. Am J Trop Med Hyg 2015;92(Suppl 6):105.
[60] Tabernero P, Mayxay M, Culzoni MJ, Dwivedi P, Swamidoss I, Allan EL, Khanthavong M, Phonlavong C, Vilayhong C, Yeuchaixiong S. A repeat random survey of the prevalence of falsified and substandard antimalarials in the Lao PDR: a change for the better. Am J Trop Med Hyg 2015;92(Suppl 6):95.
[61] Bernard M, Akrout W, Van Buu CT, Metz C, Antignac M, Yagoubi N, Do B. Liquid chromatography with tandem mass spectrometry for the simultaneous identification and quantification of cardiovascular drugs applied to the detection of substandard and falsified drugs. J Separ Sci 2015;38(4):562–70.
[62] Pathak R, Gaur V, Sankrityayan H, Gogtay J. Tackling counterfeit drugs: the challenges and possibilities. Pharmaceutical Medicine; 2023. p. 1–10.
[63] Antignac M, Diop IB, de Terline DM, Bernard M, Do B, Ikama MS, N'Guetta R, Balde DM, Tchabi Y, Aly AS. Falsified and substandard cardiovascular drugs in Africa: a need for continued monitoring strategies. Journal of Global Health 2019;9(2).
[64] Arens AM, van Wijk XM, Vo KT, Lynch KL, Wu AH, Smollin CG. Adverse effects from counterfeit alprazolam tablets. JAMA Intern Med 2016;176(10):1554–5.
[65] Amankwah-Amoah J. COVID-19 and counterfeit vaccines: global implications, new challenges and opportunities. Health policy and technology 2022;11(2):100630.
[66] Taylor E, Banyard AC, Bourhy H, Cliquet F, Ertl H, Fehlner-Gardiner C, Horton DL, Mani RS, Müller T, Rupprecht CE. Avoiding preventable deaths: the scourge of counterfeit rabies vaccines. Vaccine 2019;37(17):2285–7.
[67] Srivastava K. Fake covid vaccines boost the black market for counterfeit medicines. Br Med J 2021;375.
[68] Williams L, McKnight E. The real impact of counterfeit medications. US Pharmacists 2014;39(6):44–6.
[69] da Costa JAC, de Lourdes Aguiar-Oliveira M, Brown D, Bermudez JAZ, Netto EJR, de Lima Leitão O, de Almeida AECC, Siqueira MM. Ensuring vaccine safety: case studies of falsified influenza vaccines detected in Brazil. Vaccine X 2023;14:100343.
[70] Chang L, Lim BCW, Flaherty GT, Torresi J. Travel vaccination recommendations and infection risk in HIV-positive travellers. J Trav Med 2019;26(6):taz034.
[71] Chen LH, Hochberg NS, Control CfD. And Prevention, *The pre-travel consultation*. CDC health information for international travel; 2014. p. 26–32.
[72] Islam MR, Yoshida N, Kimura K, Uwatoko C, Rahman MS, Kumada S, Endo J, Ito K, Tanimoto T, Zin T. An investigation into the quality of medicines in Yangon, Myanmar. Pharmacy 2018;6(3):96.
[73] Sakuda M, Yoshida N, Takaoka T, Sanada T, Rahman MS, Tanimoto T, Zin T, Kimura K, Tsuboi H. Substandard and falsified medicines in Myanmar. Pharmacy 2020;8(1):45.
[74] Darina T, Ningying M. Problems of fake anti-malarial drugs in Cambodia. Cambodia/Asian Journal of Social Pharmac 2017;12(2):64–70.
[75] Lon CT, Tsuyuoka R, Phanouvong S, Nivanna N, Socheat D, Sokhan C, Blum N, Christophel EM, Smine A. Counterfeit and substandard antimalarial drugs in Cambodia. Trans R Soc Trop Med Hyg 2006;100(11):1019–24.
[76] Yoshida N, Yuasa M, Sovannarith T, Dararth E, Keila T, Kiet HB, Tsuboi H, Tanimoto T, Kimura K. A cross-sectional investigation for verification of globalization of falsified medicines in Cambodia, indicated by tablets of sildenafil citrate. Pharmacy 2019;7(3):111.
[77] Lamy M, Liverani M. Tackling substandard and falsified medicines in the Mekong: national responses and regional prospects. Asia Pac Policy Stud 2015;2(2):245–54.
[78] Han J. The health and economic impact of substandard and falsified antimalarials in Myanmar. In: Pharmacy. University of North Carolina; 2020.
[79] Nayyar GM, Breman JG, Newton PN, Herrington J. Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa. Lancet Infect Dis 2012;12(6):488–96.
[80] Newton PN, Hampton CY, Alter-Hall K, Teerwarakulpana T, Prakongpan S, Ruangveerayuth R, White NJ, Day NP, Tudino MB, Mancuso N. Characterization of "Yaa Chud" medicine on the Thailand–Myanmar border: selecting for drug-resistant malaria and threatening public health. Am J Trop Med Hyg 2008;79(5):662.
[81] Aung PL, Aung HNM, Ko KK, Aung HP. Availability of anti-malaria drugs in markets and selling behaviors of drug vendors. MMJ; 2017.
[82] Lamy MCM. Framing the challenge of poor-quality medicines: problem definition and policy making in Cambodia, Laos, and Thailand. London School of Hygiene & Tropical Medicine; 2017.
[83] Renschler JP, Walters KM, Newton PN, Laxminarayan R. Estimated under-five deaths associated with poor-quality antimalarials in sub-Saharan Africa. Am J Trop Med Hyg 2015;92(Suppl 6):119.
[84] Atukunda EC, Anne F. An evaluation of factors affecting drug quality: evidence from the antimalarial market in Uganda. of Boston: University; 2015.
[85] Beargie SM, Higgins CR, Evans DR, Laing SK, Erim D, Ozawa S. The economic impact of substandard and falsified antimalarial medications in Nigeria. PLoS One 2019;14(8):e0217910.
[86] Otte WM, van Diessen E, van Eijsden P, van der Maas F, Patsalos PN, Newton PN, Alvarenga IC, Braun KP, Sander JW. Counterfeit antiepileptic drugs threaten community services in Guinea-Bissau and Nigeria. Lancet Neurol 2015;14(11):1075–6.
[87] Antignac M, Diop BI, de Terline DM, Bernard M, Do B, Ikama SM, N'Guetta R, Balde DM, Tchabi Y, Aly AS. Fighting fake medicines: first quality evaluation of cardiac drugs in Africa. Int J Cardiol 2017;243:523–8.
[88] Kaur H, Goodman C, Thompson E, Thompson K-A, Masanja I, Kachur SP, Abdulla S. A nationwide survey of the quality of antimalarials in retail outlets in Tanzania. PLoS One 2008;3(10):e3403.
[89] Kayumba P, Risha P, Shewiyo D, Msami A, Masuki G, Ameye D, Vergote G, Ntawukuliryayo J, Remon JP, Vervaet C. The quality of essential antimicrobial and antimalarial drugs marketed in Rwanda and Tanzania: influence of tropical storage conditions on in vitro dissolution. J Clin Pharm Therapeut 2004;29(4):331–8.
[90] Höllein L, Kaale E, Mwalwisi YH, Schulze MH, Holzgrabe U. Routine quality control of medicines in developing countries: analytical challenges, regulatory infrastructures and the prevalence of counterfeit medicines in Tanzania. TrAC, Trends Anal Chem 2016;76:60–70.
[91] Kamba PF, Ireeta ME, Balikuna S, Kaggwa B. Threats posed by stockpiles of expired pharmaceuticals in low-and middle-income countries: a Ugandan perspective. Bull World Health Organ 2017;95(8):594.
[92] Newton PN, Hanson K, Goodman C. Do anti-malarials in Africa meet quality standards? The market penetration of non quality-assured artemisinin combination therapy in eight African countries. Malar J 2017;16:1–21.
[93] Fatokun O. Curbing the circulation of counterfeit medicines in Nigeria. Lancet 2016;388(10060):2603.
[94] Ekoh PC, Chukwemeka E, Ezulike CD, George EO, Egbo IE, Agbawodikeizu PU, Anthony IO, Nnebe I. Ageing and health in Africa: assessing how low-and middle-class older adults with chronic illnesses navigate the problem of counterfeit drugs in Nigeria. Journal of Population Ageing 2022;15(4):981–97.
[95] Cartwright R, Barić A. The rise of counterfeit pharmaceuticals in Africa. https://enact-africa.s3.amazonaws.com/site/uploads/2018-11-12-counterfeit-medicines-policy-brief.pdf; 2018 Oct 14 2023.
[96] Basco LK. Molecular epidemiology of malaria in Cameroon. XIX. Quality of antimalarial drugs used for self-medication. Am J Trop Med Hyg 2004;70(3):245–50.
[97] Stumpf SA, Chaudhry P. Country matters: executives weigh in on the causes and counter measures of counterfeit trade. Bus Horiz 2010;53(3):305–14.
[98] Verma S, Kumar R, Philip P. The business of counterfeit drugs in India: a critical evaluation. Int J Manag Int Bus Stud 2014;4(2):141–8.
[99] Shukla N, Sangal T. Generic drug industry in India: the counterfeit spin. Journal of Intellectual Property Rights 2009.
[100] Chatterjee P. India combats confusion over counterfeit drugs. Lancet 2010;375(9714):542.
[101] Verma S, Kumar R, Philip P. IPR issues in counterfeiting: a critical evaluation of Indian pharmaceutical sector. Elsevier Publications; 2014.
[102] Shah NA, Sattigeri BM, Patel NN, Desai HA. Counterfeit drugs in India: significance and impact on pharmacovigilance. Int J Res Med Sci 2015.
[103] Mamtashanti M, Rahul J, Kashyap T. A review on regulatory requirements to prevent counterfeit drugs in India. International Journal of Pharmaceutical Investigation 2020;10(3).
[104] Khan A, Khar R. Current scenario of spurious and substandard medicines in India: a systematic review. Indian J Pharmaceut Sci 2015;77(1):2.
[105] Lancet T. Vaccine scandal and confidence crisis in China. 2018. p. 360.
[106] Yuan X. China's vaccine production scare. Lancet 2018;392(10145):371.
[107] Binkowska-Bury M, Januszewicz P, Wolan M, Sobolewski M, Krauze M, Fijalek ZE. Counterfeit medicines in Poland: opinions of primary healthcare physicians, nurses and lay persons. J Clin Nurs 2013;22(3–4):559–68.

[108] Chiang J, Yafi FA, Dorsey Jr PJ, Hellstrom WJ. *The dangers of sexual enhancement supplements and counterfeit drugs to "treat" erectile dysfunction.* Translational. andrology and urology 2017;6(1):12.
[109] Shevchuk VM, Parfylo IV, Sokolenko MO. Falsification of medicines and distribution of falsified medicines in Ukraine: criminalistic means of detection and counteraction. Wiad Lek 2021:2946.
[110] Eiben H, Hala L, Slipchuk V. The current state of the pharmaceutical market of Ukraine, quality assurance and falfication of medicines. Pharmacia 2021;68(2): 411–9.
[111] Clark F. Rise in online pharmacies sees counterfeit drugs go global. Lancet 2015; 386(10001):1327–8.
[112] Fayzrakhmanov N. Fighting trafficking of falsified and substandard medicinal products in Russia. Int J Risk Saf Med 2015;27(s1):S37–40.
[113] Kuzmenko O, Matselyk T, Chorna V. Financial offenses in the circulation of medicines in the context of globalization. Baltic Journal of Economic Studies 2018;4(5):140–4.
[114] Attaran A, Bate R, Kendall M. Why and how to make an international crime of medicine counterfeiting. J Int Crim Justice 2011;9(2):325–54.
[115] Rojas-Cortés R. Substandard, falsified and unregistered medicines in Latin America, 2017-2018, vol. 44. Revista panamericana de salud publica; 2020.
[116] Medina E, Bel E, Suñé JM. Counterfeit medicines in Peru: a retrospective review (1997–2014). BMJ Open 2016;6(4):e010387.
[117] Bate R, Mathur A. Corruption and medicine quality in Latin America: a pilot study. B E J Econ Anal Pol 2018;18(2):20170076.
[118] Fittler A, Bősze G, Botz L. Evaluating aspects of online medication safety in long-term follow-up of 136 Internet pharmacies: illegal rogue online pharmacies flourish and are long-lived. J Med Internet Res 2013;15(9):e2606.
[119] Alwon BM, Solomon G, Hussain F, Wright DJ. A detailed analysis of online pharmacy characteristics to inform safe usage by patients. Int J Clin Pharm 2015; 37:148–58.
[120] Smolka K, Gronwald K. Operation Pangea–standing together in combat against international pharmaceutical crime. Bundesgesundheitsblatt - Gesundheitsforsch - Gesundheitsschutz 2017;60:1233–9.
[121] Ofori-Parku SS. Fighting the global counterfeit medicines challenge: a consumer-facing communication strategy in the US is an imperative. Journal of Global Health 2022;12.
[122] Fittler A, Vida RG, Káplár M, Botz L. Consumers turning to the internet pharmacy market: cross-sectional study on the frequency and attitudes of Hungarian patients purchasing medications online. J Med Internet Res 2018;20(8):e11115.
[123] Lee KS, Yee SM, Zaidi STR, Patel RP, Yang Q, Al-Worafi YM, Ming LC. Combating sale of counterfeit and falsified medicines online: a losing battle. Front Pharmacol 2017;8:268.
[124] Long CS, Kumaran H, Goh KW, Bakrin FS, Ming LC, Rehman IU, Dhaliwal JS, Hadi MA, Sim YW, Tan CS. Online pharmacies selling prescription drugs: systematic review. Pharmacy 2022;10(2):42.
[125] Gallagher CT, Chapman LE. Classification, location and legitimacy of web-based suppliers of Viagra to the UK. Int J Pharm Pract 2010;18(6):341–5.
[126] White CM. Counterfeit drugs: a major issue for vulnerable citizens throughout the world and in the United States. J Am Pharmaceut Assoc 2021;61(1):e93–8.
[127] Customs & Border Protection. The truth behind counterfeits. Sept 21 2023]; Available from: https://www.cbp.gov/trade/fakegoodsrealdangers; 2023.
[128] Mackey TK, Cuomo R, Guerra C, Liang BA. After counterfeit Avastin®—what have we learned and what can be done? Nat Rev Clin Oncol 2015;12(5):302–8.
[129] Cuomo RE, Mackey TK. An exploration of counterfeit medicine surveillance strategies guided by geospatial analysis: lessons learned from counterfeit Avastin detection in the US drug supply chain. BMJ Open 2014;4(12):e006657.
[130] Friedman J, Godvin M, Molina C, Romero R, Borquez A, Avra T, Goodman-Meza D, Strathdee S, Bourgois P, Shover CL. Fentanyl, heroin, and methamphetamine-based counterfeit pills sold at tourist-oriented pharmacies in Mexico: an ethnographic and drug checking study. Drug Alcohol Depend 2023: 110819.
[131] Jackson G, Patel S, Khan S. Assessing the problem of counterfeit medications in the United Kingdom. Int J Clin Pract 2012;66(3):241–50.
[132] Frangež D, Slak B. Online counterfeit medicine trade in Slovenia. In: Criminal justice and security in Central and Eastern Europe: safety, security, and social control in local communities: conference proceedings; 2016.
[133] EUROPOL. Intellectual priperty crime threat assessment 2022. 2022. : Brussels.
[134] Loutan L. Malaria: still a threat to travellers. Int J Antimicrob Agents 2003;21(2): 158–63.
[135] Kain KC, Keystone JS. Malaria in travelers: epidemiology, disease, and prevention. Infectious Disease Clinics 1998;12(2):267–84.
[136] Angelo KM, Libman M, Caumes E, Hamer DH, Kain KC, Leder K, Grobusch MP, Hagmann SH, Kozarsky P, Lalloo DG. Malaria after international travel: a GeoSentinel analysis, 2003–2016. Malar J 2017;16:1–9.
[137] Amin AA, Hughes DA, Marsh V, Abuya TO, Kokwaro GO, Winstanley PA, Ochola SA, Snow RW. The difference between effectiveness and efficacy of antimalarial drugs in Kenya. Trop Med Int Health 2004;9(9):967–74.
[138] Bate R, Coticelli P, Tren R, Attaran A. Antimalarial drug quality in the most severely malarious parts of Africa–a six country study. PLoS One 2008;3(5): e2132.
[139] Brower V. Falsified and substandard malaria drugs in Africa. Lancet Infect Dis 2017;17(10):1026–7.
[140] Savi MK. An overview of malaria transmission mechanisms, control, and modeling. Med Sci 2022;11(1):3.
[141] Whiteside A, Wilson D. Health and AIDS in 2019 and beyond. v: Taylor & Francis; 2018iii.
[142] Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievlan DR, Colombara DV, Ikuta KS, Kissoon N, Finfer S. Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. Lancet 2020;395(10219):200–11.
[143] Naghavi M, Abajobir AA, Abbafati C, Abbas KM, Abd-Allah F, Abera SF, Aboyans V, Adetokunboh O, Afshin A, Agrawal A. Global, regional, and national age-sex specific mortality for 264 causes of death, 1980–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet 2017;390(10100): 1151–210.
[144] Goodman C, Brieger W, Unwin A, Mills A, Meek S, Greer G. Medicine sellers and malaria treatment in sub-Saharan Africa: what do they do and how can their practice be improved? Am J Trop Med Hyg 2007;77(6 Suppl):203.
[145] Dégardin K, Roggo Y, Margot P. Understanding and fighting the medicine counterfeit market. J Pharmaceut Biomed Anal 2014;87:167–75.
[146] Mackey TK, Liang BA. The global counterfeit drug trade: patient safety and public health risks. J Pharmaceut Sci 2011;100(11):4571–9.
[147] Jang SH, Ko LK, Meischke H. Factors associated with buying medications abroad by nativity and race/ethnicity in the US. J Immigr Minority Health 2020;22: 1184–92.
[148] Patel K, Chotai N. Pharmaceutical GMP: past, present, and future–a review. Die Pharmazie-An International Journal of Pharmaceutical Sciences 2008;63(4): 251–5.
[149] Karmacharya JB. Good manufacturing practices (GMP) for medicinal products. Promising Pharmaceuticals 2014:101.
[150] Harris JR. Good manufacturing practices (GMP) and related FDA guidelines. Pharmaceutical Manufacturing Handbook: Regulations and Quality 2008:1–115.
[151] Grazal JG, Earl DS. EU and FDA GMP regulations: overview and comparison. Qual Assur J: The Quality Assurance Journal for Pharmaceutical, Health and Environmental Professionals 1997;2(2):55–60.
[152] Ziance RJ. Roles for pharmacy in combatting counterfeit drugs. J Am Pharmaceut Assoc 2008;48(4):e71–91.
[153] Gaudiano MC, Manna L, Rodomonte AL, Bartolomei M, Bertocchi P, Gallinella B, Antoniella E, Muleri N, Civitelli G, Alimonti S. A survey on illegal and counterfeit medicines for the treatment of erectile dysfunctions in Italy. J Sex Med 2012;9(8): 2130–7.
[154] Newton P, Proux S, Green M, Smithuis F, Rozendaal J, Prakongpan S, Chotivanich K, Mayxay M, Looareesuwan S, Farrar J. Fake artesunate in southeast Asia. Lancet 2001;357(9272):1948–50.
[155] Drugs C. Guidelines for the development of measures to combat counterfeit drugs. Geneva: WHO; 1999. p. 1–60.
[156] Syhakhang L, Lundborg CS, Lindgren B, Tomson G. The quality of drugs in private pharmacies in Lao PDR: a repeat study in 1997 and 1999. Pharm World Sci 2004; 26:333–8.
[157] Onwujekwe O, Kaur H, Dike N, Shu E, Uzochukwu B, Hanson K, Okoye V, Okonkwo P. Quality of anti-malarial drugs provided by public and private healthcare providers in south-east Nigeria. Malar J 2009;8:1–9.
[158] Taylor R, Shakoor O, Behrens R, Everard M, Low A, Wangboonskul J, Reid R, Kolawole J. Pharmacopoeial quality of drugs supplied by Nigerian pharmacies. Lancet 2001;357(9272):1933–6.
[159] Green, M.D., Counterfeit drugs - CDC health information for international travel 2012: the Yellow Book, in CDC health information for international travel 2012: the Yellow Book. 2011, centres for disease control. p. 126.
[160] Hall C. Technology for combating counterfeit medicine. Pathog Glob Health 2012;106(2):73–6.
[161] Gupta P, Singhal K, Pandey A. Counterfeit (fake) drugs & new technologies to identify it in India. Int J Pharmaceut Sci Res 2012;3(11):4057.
[162] Ekeigwe AA. Drug manufacturing and access to medicines: the West African story. A literature review of challenges and proposed remediation. AAPS Open 2019;5 (1):3.
[163] Obi-Eyisi O, Wertheimer A. The background and history of counterfeit medicines. Counterfeit Medicines: Policy, Economics and Countermeasure 2012.
[164] Khan AY, Ghilzai NMK. Counterfeit and substandard quality of drugs: the need for an effective and stringent regulatory control in India and other developing countries. Indian J Pharmacol 2007;39(4):206.
[165] Pascu GA, Hancu G, Rusu A. Pharmaceutical serialization, a global effort to combat counterfeit medicines. Acta Marisiensis-Seria Medica 2020;66(4):132–9.
[166] Khan MH, Okumura J, Sovannarith T, Nivanna N, Akazawa M, Kimura K. Prevalence of counterfeit anthelminthic medicines: a cross-sectional survey in Cambodia. Trop Med Int Health 2010;15(5):639–44.
[167] Mullaicharam A. *Counterfeit herbal medicine.* International journal of nutrition. Pharmacology, Neurological Diseases 2011;1(2):97–102.
[168] Vorrath J, Voss M. The hidden dangers of falsified and substandard medicines: developing countries are most affected by the illegal trade. 2019.
[169] Alfarsi A, Caillet C, Fawbert G, Lawrence S, Krüse J, McSweeney S, O'Mahony M, Dondorp A, Newton PN, Fitzpatrick D. Sounding out falsified medicines from genuine medicines using Broadband Acoustic Resonance Dissolution Spectroscopy (BARDS). Sci Rep 2021;11(1):12643.
[170] Włodarczak U, Swieczkowski D, Religioni U, Jaguszewski M, Krysinski J, Merks P. Awareness of the implementation of the falsified medicines directive among pharmaceutical companies' professionals in the European economic area. Pharm Pract 2017;15(4).
[171] Cozzella L, Simonetti C, Spagnolo GS. Drug packaging security by means of white-light speckle. Opt Laser Eng 2012;50(10):1359–71.
[172] Buowari O. Fake and counterfeit drug: a review. Afrimedic Journal 2012;3(2): 1–4.

[173] Sekhar MS, Mary CA, George RM, Sasidharan S. Counterfeit medicines: a real threat to the society. Int J Pharmaceut Sci Res 2011;2(7):1645.
[174] Ho HMK, Xiong Z, Wong HY, Buanz A. The era of fake medicines: investigating counterfeit medicinal products for erectile dysfunction disguised as herbal supplements. Int J Pharm 2022;617:121592.
[175] Borup R, Kaae S, Minssen T, Traulsen J. Fighting falsified medicines with paperwork–a historic review of Danish legislation governing distribution of medicines. Journal of Pharmaceutical Policy and Practice 2016;9:1–8.
[176] Wertheimer AI, Norris J. Safeguarding against substandard/counterfeit drugs: mitigating a macroeconomic pandemic. Res Soc Adm Pharm 2009;5(1):4–16.
[177] Sahoo M, Singhar SS, Sahoo SS. A blockchain based model to eliminate drug counterfeiting. In: Machine learning and information processing: proceedings of ICMLIP 2019. Springer; 2020.
[178] Kumar R, Tripathi R. Traceability of counterfeit medicine supply chain through Blockchain. In: 2019 11th international conference on communication systems & networks (COMSNETS). IEEE; 2019.
[179] Bates NC, Discounts Deadly. How reimportation jeopardizes the safety of the US pharmaceutical drug supply under the federal trade commission amendment. bepress Legal Series 2005:833.
[180] Morris J, Stevens P. Counterfeit medicines in less developed countries. International Policy Network 2006. London.
[181] Kumar B, Baldi A. The challenge of counterfeit drugs: a comprehensive review on prevalence, detection and preventive measures. Curr Drug Saf 2016;11(2):112–20.
[182] Patel A, Norris P, Gauld R, Rades T. Drug quality in South Africa: perceptions of key players involved in medicines distribution. Int J Health Care Qual Assur 2009;22(5):547–60.
[183] Caudron JM, Ford N, Henkens M, Macé C, Kiddle-Monroe R, Pinel J. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. Trop Med Int Health 2008;13(8):1062–72.
[184] Chambliss WG, Carroll WA, Kennedy D, Levine D, Moné MA, Ried LD, Shepherd M, Yelvigi M. Role of the pharmacist in preventing distribution of counterfeit medications. J Am Pharmaceut Assoc 2012;52(2):195–9.
[185] Bashir A, Galal S, Ramadan A, Wahdan A, El-Khordagui L. Community pharmacists' perceptions, awareness and practices regarding counterfeit medicines: a cross-sectional survey in Alexandria, Egypt. East Mediterr Health J 2020;26(5):556–64.
[186] Adigwe OP. The role of pharmacists in eliminating counterfeit medicines in Nigeria. Front Public Health 2023;11.
[187] Alfadl AA, Hassali MA, Ibrahim MIM. Counterfeit drug demand: perceptions of policy makers and community pharmacists in Sudan. Res Soc Adm Pharm 2013;9(3):302–10.
[188] Acosta RW, Wolfe MS. Chapter 5 - structure and organization of the pre-travel consultation and general advice for travelers. In: Keystone JS, et al., editors. Travel medicine. second ed.). Edinburgh: Mosby; 2008. p. 35–45.
[189] Acosta RW. Chapter 2 - the pre-travel consultation. In: Brunette GW, et al., editors. CDC health information for international travel 2010. Edinburgh: Mosby; 2009. p. 19–241.
[190] Lee PR, Herzstein J. International drug regulation. Annu Rev Publ Health 1986;7(1):217–35.
[191] WHO. Assessment of medicines regulatory systems in sub-Saharan African countries. An overview of findings from 26 assessment reports. Geneva: WHO; 2010.
[192] Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines regulation in Africa: current state and opportunities. Pharmaceut Med 2017;31:383–97.
[193] McGinnis M. Media reports on medicine quality: focusing on USAID-assisted countries. Promoting quality of medicines program. Rockville, MD: United States Pharmacopeia; 2013.
[194] Burki T. Building medical regulatory authorities in Africa. Lancet Infect Dis 2010;10(4):222.
[195] Mackey TK. Global health diplomacy and the governance of counterfeit medicines: a mapping exercise of institutional approaches. J Health Diplomacy 2013;1(1).
[196] WHO. *WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce* 2011 Oct 16 2023]; Available from: https://apps.who.int/gb/sf/pdf_files/A_SSFFC_WG4-en.pdf.
[197] Mackey TK, Liang BA. Improving global health governance to combat counterfeit medicines: a proposal for a UNODC-WHO-Interpol trilateral mechanism. BMC Med 2013;11(1):1–10.
[198] Nayyar GM, Attaran A, Clark JP, Culzoni MJ, Fernandez FM, Herrington JE, Kendall M, Newton PN, Breman JG. Responding to the pandemic of falsified medicines. Am J Trop Med Hyg 2015;92(Suppl 6):113.
[199] European Parliment. Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Official Journal of the European Union OJEU; 2011.
[200] Smith G, Smith J, Brindley D. The Falsified Medicines Directive: how to secure your supply chain. London, England: SAGE Publications Sage UK; 2014. p. 169–72.
[201] Koenraadt R, van de Ven K. The Internet and lifestyle drugs: an analysis of demographic characteristics, methods, and motives of online purchasers of illicit lifestyle drugs in The Netherlands. Drugs Educ Prev Pol 2018;25(4):345–55.
[202] INTERPOL. Online sale of fake medicines and products targeted in INTERPOL operation. https://www.interpol.int/en/News-and-Events/News/2016/Online-sale-of-fake-medicines-and-products-targeted-in-INTERPOL-operation; 2016 Oct 13 2023.
[203] INTERPOL. USD 11 million in illicit medicines seized in global INTERPOL operation. https://www.interpol.int/en/News-and-Events/News/2022/USD-11-million-in-illicit-medicines-seized-in-global-INTERPOL-operation; 2022 Oct 23 2023.
[204] WCO. 501.5 million items seized and participation of 160 WCO Members in Operation STOP II 2022 Oct 23 2023. Available from: https://www.wcoomd.org/en/media/newsroom/2022/june/operation-stop-ii.aspx#:~:text=From_2030_20April_202021_20to,and_20medical_20devices_20related_20to.
[205] WCO. Operation STOP: the WCO operation hits hard the illegal trafficking linked to COVID-19. https://www.wcoomd.org/en/media/newsroom/2020/october/operation-stop–the-wco-operation-hits-hard-the-illegal-trafficking-linked-to-covid19.aspx; 2020 Oct 23 2023.